## Remarks

Claims 1, 9 and 36-37 have been amended. Claims 1-10, 36-37 and 40-64 will be pending in the present application upon entry of this amendment. Claims 10 and 58-64 are currently withdrawn from consideration.

Basis for the amendment to claim 1 can be found on page 8, lines 25-27 of the specification. Claim 9 has been amended to correct a minor typographical error. Basis for the amendment to claim 36 can be found at page 13, line 36 to page 14, line 10 of the specification. Basis for the amendments to claim 37 can be found in Fig. 2 and page 8, lines 13-15 and 25-27 since the specification discloses that the annular member may deform by plastic deformation and that the staple-like elements are preferably formed from the same material as the annular member and thus may also deform by plastic deformation.

The specification was objected to on the basis that it was not in the proper format. The applicant has amended the specification to add the appropriate headings and place it in the proper format. The specification was also objected to on the basis that the Title of the Invention is not descriptive. A new title of the invention has been provided in order to overcome this objection. Favorable consideration and withdrawal of the objections to the specification are requested in view of these amendments.

Claim 36 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite on the basis that the recitation of the main plane and center line of the connector being at an angle to one another does not specify whether this is the case in the starting position, joining position or both. Claim 36 has been amended to indicate that the main plane and the center line of the connector are at an angle to one another in the starting position in order to overcome this objection. Basis for this amendment can be found in Fig. 14 and the accompanying description of Fig. 14 found at page 13, lines 22-35 of the specification. Favorable consideration and withdrawal of the rejection of claim 36 under 35 U.S.C. §112, in view of the amendment is requested.

Claim 37 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite on the basis that there is insufficient antecedent basis for the center line of the claim. Claim 37 has been amended to provide antecedent basis for the center line in order to overcome this rejection. Favorable consideration and withdrawal of the rejection of claim 37 under 35 U.S.C. §112, in view of the amendment is requested.

Claims 1-7, 36-37, 40-43 and 46-51 have been rejected under 35 U.S.C. §102(a) and/or (e) as being anticipated by U.S. Patent no. 6,391,036 (hereinafter, "Berg et al."). This rejection is respectfully traversed and reconsideration is requested for the reasons that follow.

The present invention, as claimed in independent claim 1, now requires that the annular member be permanently deformable by expansion via plastic deformation. Plastic deformation is a process whereby the annular member is permanently deformed from a first position to a second joining position by application of force from an external source. For example, in the embodiment of Figs. 1-3, the sinusoidal annular member is permanently deformed by application of force from a separate applicator to cause the curved portions of the sinusoidal annular member to at least partially straighten thereby increasing the size of the annular member.

Thus, the property of the device of claim 1 that permits plastic deformation of the annular member distinguishes the device of claim 1 from the device of Berg et al. since the device of Berg et al. relies on elastic deformation. In the case of plastic deformation, as in the present invention, the device has the property that if sufficient force is exerted on the device, the device will permanently deform to a new position or shape. In the case of elastic deformation, as in Berg et al., if sufficient force is exerted on the device it will deform but, once that force is removed, the device will return to its original position or shape as a result of elastic deformation due to the resilience of the device and the property of the material of Berg et al. that it has "memory" of its original shape. See e.g. col. 2, lines 16-31 of Berg et al.

This difference is illustrated by the applicator used in Berg et al. Specifically, Berg et al. employs a delivery tube 40 that exerts a force on the connector 20 of Berg et al. In Berg et al, delivery tube 40 elastically deforms fingers 14 from a substantially radial position to a substantially axial position by confining fingers 14 within delivery tube 40. When delivery tube 40 is removed, fingers 14 of the Berg et al. connector 20 return to their original, substantially radial position using elastic deformation by virtue of the "memory" of the material used to form fingers 14. See e.g. col. 2, lines 16-31 and col. 5, lines 33-51 of Berg et al.

In another embodiment of Berg et al., both fingers 14 and medial portion 16 are elastically deformed by delivery tube 40 and, upon removal of delivery tube 40, both fingers 14 and medial portion 16 return to their original position by elastic deformation due to the "memory" of the material from which the fingers 14 and medial portion 16 are made. See e.g. col. 7, lines 33-45 of Berg et al. regarding elastic deformation of the medial portion 16.

Thus, one important difference between the device of claim 1 of the present application and the device of Berg et al. is that the annular member of claim 1 of the present application permanently deforms from a first position to a second position by plastic deformation, whereas the device of Berg et al. does not permanently deform by plastic deformation, but instead returns to its original shape by elastic deformation upon removal of an external force exerted on the device of Berg et al. This difference is significant since it influences the possible geometric configurations of the devices that can be employed to perform anastomoses. For example, in the device of the present invention, the applicator can be located within the lumen of the annular member and still function to permanently deform the annular member, as required. In contrast, in the device of Berg et al., the delivery tube 40 (applicator) must be located outside the connector 20 to accomplish its function of constraining the highly elastic fingers 14 during delivery of the device of Berg et al. to the anastomosis site.

Finally, there appears to be no teaching or suggestion in Berg et al. to employ plastic deformation for the purpose of permanently deforming either the fingers 14 or the medial portion 16 from a first position, to a second, joining position, as is required by the present claims.

Accordingly, since at least one element of independent claim 1, as amended, is not taught or suggested by Berg et al., it is considered that independent claim 1, as amended, is novel over Berg et al. for at least this reason. Claims 2-9 and 40-57 all depend from claim 1 and thus are considered patentable over Berg et al. for at least the same reason as given for claim 1. Accordingly, favorable consideration and withdrawal of the rejection of claims 1-7, 40-43 and 46-51 under 35 U.S.C. §102(a) and/or (e) over Berg et al. is requested.

Independent claim 36, as amended, relates to a connector wherein the center line of the annular member is at an angle to the main plane of the annular member such that upon deformation of said connector to said joining position at an anastomosis site, an elliptical anastomosis is formed. Berg et al. does not teach or suggest the provision of a connector having the structure claimed in claim 36 to thereby form an elliptical anastomosis when deformed at the anastomosis site. Rather, if Berg et al. desires to form an elliptical anastomosis, Berg et al. teaches that the connector should be elliptical in shape. See e.g. col. 7, lines 63-65 of Berg et al. This has the disadvantage that an elliptical passageway into the body will have to be made to permit insertion of the elliptical connector of Berg et al. In contrast, the configuration of the device of claim 36 permits use of a circular passageway for insertion of the device into the body, while providing the ability to make an elliptical anastomosis. As explained on page 14, lines 1-10, this configuration of the device of the present invention allows formation of an elliptical orifice in the vessel wall with a cross-sectional

area larger than the cross-sectional area of a circular passageway required to insert the connector into the body. In the Berg et al. device, however, because the shape of the device should be elliptical to provide an elliptical anastomosis, the cross-sectional area of the passageway required to insert the connector into the body will have to be the same as the cross-sectional area of the orifice of the anastomosis.

Berg et al. also suggests skewing one or both ends of the medial portion 16 relative to the longitudinal axis of the connector for the purpose of connecting the end of a graft to the sidewall of a patient's body conduit at an angle other than 90 degrees to that sidewall. However, Berg et al. does not teach or suggest a device which angles the main plane of the connector relative to the center line, as presently claimed, in order to obtain an elliptical anastomosis, as is the case for the device of claim 36 of the present application. Accordingly, favorable consideration and withdrawal of the rejection of claim 36 under 35 U.S.C. §102(a) and/or (e) over Berg et al. is requested.

Independent claim 37 of the present application relates to a connector wherein the staple-like elements are permanently deformable by plastic deformation. As explained above with respect to claim 1, Berg et al. relates to a connector that employs elastic deformation rather than plastic deformation. As a result, the connector of Berg et al. has different properties than the connector of claim 37 the present application since the Berg et al. device must have "memory" such that it reverts to its original shape upon removal of an external force exerted on the device. In contrast, the staple-like elements of the present invention, upon application of an external force, permanently deform from a first starting position to a second joining position via plastic deformation. Berg et al. does not teach or suggest that the fingers 14 of the Berg et al. device should undergo plastic deformation, but instead suggest that the fingers 14 should be highly elastic. Thus, claim 37 is considered to be novel over Berg et al. for at least this reason. Accordingly, favorable consideration and withdrawal of the rejection of claim 37 under 35 U.S.C. §102(a) and/or (e) over Berg et al. is requested.

Claims 8-9 have been rejected under 35 U.S.C. §103(a) over Berg et al. in view of U.S. Patent no. 5,104,399 (hereinafter, "Lazarus et al."). This rejection, at least insofar as it applies to claims 8-9, as amended, is respectfully traversed and reconsideration is requested for the reasons which follow.

Claims 8-9 are considered patentable over a combination of Berg et al. in view of Lazarus et al. at least because claims 8-9, by virtue of their dependence on claim 1, require that the annular member permanently deform from a first starting position to a second joining position via plastic deformation. As discussed above with respect to the rejection of claim 1, Berg et al. does not teach

or suggest this feature of claims 8-9. Moreover, it would not be obvious to modify the connector of Berg et al. to substitute a connector that deforms by plastic deformation since the Berg et al. device would no longer function for its intended purpose if this change were made. Specifically, if the Berg et al. connector 20 were deformable by plastic deformation from a first position to a second position, then the Berg et al. connector 20 would remain in the compressed position that is caused by insertion of connector 20 into a delivery tube 40 as discussed at col. 7, lines 30-45 of Berg et al. As a result, the connector 20 of Berg et al. would not return to its original shape as is required by the Berg et al. device (see col. 7, lines 37-41 of Berg et al.) to make a suitable anastomosis. In fact, Berg et al. teaches away from modification of the Berg et al. device to employ plastic deformation at col. 7, lines 27-30 where Berg et al. states,

> "The radial compliance of a flexible connector or plug (i.e. the ability of such a structure to resiliently increase or decrease in circumference) is believed to be beneficial with respect to long-term body circuit lumen patency."

This statement in Berg et al. suggests that it is desirable to maximize resilience of the connector to provide elastic deformation, rather than to reduce resilience by providing a structure that permanently deforms, as in the present invention. Accordingly, a skilled person would be motivated not to modify the device of Berg et al. in order to arrive at the device of claims 8-9 since Berg et al. teaches that resilience is a beneficial property of the Berg et al. device. Accordingly, favorable consideration and withdrawal of the rejection of claims 8-9 under 35 U.S.C. §103(a) over Berg et al. in view of Lazarus et al. is requested.

Claims 44-45 and 52-57 have been rejected under 35 U.S.C. §103(a) over Berg et al., taken alone. Claims 44-45 and 52-57, by virtue of their dependence on claim 1, also require that the annular member permanently deform from a first starting position to a second joining position by plastic deformation. For the reasons given above with respect to the rejection of claims 8-9 under 35 U.S.C. §103(a), a skilled person would not modify the device of Berg et al. to provide this feature of claims 44-45 and 52-57. Accordingly, favorable consideration and withdrawal of the rejection of claims 44-45 and 52-57 under 35 U.S.C. §103(a) over Berg et al. is requested.

Although the applicant has not specifically addressed each and every statement made by the Examiner in the Office Action since it was not necessary to do so in order to provide a complete response, this should not be interpreted as a waiver of any of applicant's arguments. Accordingly, the applicant reserves the right to contest any statement made by the Examiner in the Office Action that was not specifically addressed herein.

Favorable consideration and issuance of a notice of allowance are requested.

Respectfully submitted,

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